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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,774	10/09/2001	H. Paul Redmond	1194-180	3168

6449 7590 04/08/2003

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EXAMINER
MAIER, LEIGH C

ART UNIT	PAPER NUMBER
1623	7

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/971,774	Applicant(s) Redmond
	Examiner Leigh Maier	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-26 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☒ Interview Summary (PTO-413) Paper No(s). 3
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

New claims 13-26 have been added. Claims 1-26 are pending.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by JACOBI et al (Langenbecks Arch. Chir., 1997).

JACOBI teaches that the intraperitoneal adminstration of taurolidine or a combination of taurolidine and heparin at the time of laparoscopic surgery for tumor removal reduces the incidence of tumor growth and trocar metastases. See abstract. The reference discloses that lavage with taurolidine and heparin is performed in human patients undergoing laparoscopic resection of malignancies. See last paragraph of the reference on page S35. In this discussion of the laparoscopic procedure in human patients, the reference does not explicitly describe the use

of a trocar in this procedure in this passage. However, the reference is drawn to the decreased incidence of trocar metastases, so the use of this instrument is clearly implied.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 13-17, 20, 21, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) as applied to claims 1, 5, 8, 9, 11, and 12 above, in view of MONSON et al (WO 92/00743).

The claims are drawn to a method of treating abdominal cancer comprising perfoming surgery to remove a cancerous tumor wherein the method includes a step of administering a solution of taurolidine and/or taurultam to the patient's abdomen prior to closing surgical opening. Dependents are drawn to further limitations concerning the administration of the taurolidine/taurultam solution - administration before and/or after surgery, concentration of the solution, and administration of other components.

Claims 13 and dependents are drawn to the use of a solution *consisting essentially of* taurultam. For the purposes of examination, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If Applicant contends that additional components in the prior art are excluded by the recitation of "consisting essentially of," Applicant has the burden of showing that the introduction of components would materially change the characteristics of the instant invention.

JACOBI teaches as set forth above. The reference does not teach the use of taurultam in the concentration range recited in this procedure or the use such a solution before surgery or after closing. Neither does the reference specifically address the full range of cancer types recited in the claims.

MONSON teaches that taurolidine and taurultam are functional equivalents as antibacterials and antitumorals. See all of page 1. The reference further teaches that the agents are particularly beneficial for the prevention of the spread of metastases, especially following

surgical removal of tumors of any type, including lymphomas, sarcomas, melanomas, and carcinomas. See page 3, second paragraph. Patients in need of metastasis prevention would include those scheduled for cancer surgery and those who have had cancer surgery. The reference teaches administration of the solution by injection or infusion.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam (with or without heparin) during laparoscopic cancer surgery. MONSON had taught that these species are functional equivalents for the inhibition of metastases. In the absence of unexpected results, one of ordinary skill would reasonably expect success in the use of taurolidine and/or taurultam for this art-disclosed utility. It would be within the scope of the artisan to optimize the solution concentration with routine experimentation.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam before and/or after cancer surgery for the benefits of treating malignancies as well as prevention of metastases, taught by MONSON. It would be further obvious to use this procedure for all of the recited cancers with a reasonable expectation of success. It would be within the scope of the artisan to select any common type of adminstration, such as IV or catheter, to adminster the solution.

Claims 6, 7, 10, 18, 19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743)

as applied to claims 1-5, 8, 9, 11-17, 20, 21, 23, and 24 above, and further in view of ALLGOOD et al (US 5,176,651).

The invention is as set forth above. Claims 6, 7, 10, 18, 19, and 22 are drawn to the use of a trocar comprising passing the taurolidine and/or taurultam solution through said trocar.

JACOBI and MONSON teach as set forth above. The references are silent regarding the adminstration of the taurolidine and/or taurultam solution by passing it through a trocar.

ALLGOOD presents a brief discussion of the use of trocars and cannulas in endoscopic (laparoscopic) surgery. See col 1, lines 10-39. The reference teaches that laparoscopy typically comprises the use of a cannula inserted through a trocar for irrigation of the surgical site. By definition, irrigation comprises administration of a fluid to said site.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer taurolidine and/or taurultam in the JACOBI procedure via a cannula inserted through the trocar, as JACOBI had taught that the administration of the solution is beneficial in the prevention of trocar metastases. Fluid delivery via a cannula through a trocar in laparoscopy is standard procedure, as would be known to one of ordinary skill.

Claims 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) as applied to claims 1-5, 8, 9, 11-17, 20, 21, 23, and 24 above, and further in view of NICOLSON et al (US 5,262,403).

The invention is as set forth above. Claims 9 and 21 are drawn to the use of hyaluronic acid in combination with the taurolidine and/or taurultam.

JACOBI and MONSON teach as set forth above. The references teach the adminstration of the taurolidine and/or taurultam solution in combination with heparin but not hyaluronic acid.

NICOLSON teaches that glycosaminoglycans, such as heparin and hyaluronic acid, are useful for the inhibition of tumor-invasiveness and metastasis. See abstract and col 10, lines 4-10.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer the taurolidine and/or taurultam in combination with hyaluronic acid. JACOBI had taught that the administration of the taurolidine and/or taurultam in combination with heparin has utility in the prevention of metastasis. NICOLSON had taught that hyaluronic acid and heparin are functional equivalents for this utility. In the absence of unexpected results, one of ordinary skill would reasonably expect success in using hyaluronic acid in the JACOBI process.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) as applied to claims 1-5, 8, 9, 11-17, 20, 21, 23, and 24 above, and further in view of PHYSICIANS' DESK REFERENCE (PDR - 1995).

The invention is as set forth above. Claims 25 and 26 are drawn to the method further comprising adminstration of 5-FU at a dosage of about 0.1-1,000 mg.

JACOBI and MONSON teach as set forth above. The references do not teach the method further comprising adminstration of 5-FU. However, MONSON expressly suggests the administration of taurolidine and/or taurultam in combination with other anti-tumor therapuetics. See page 3, lines 1-7.

PDR teaches that 5-FU has utility in the treatment of a variety of the recited cancers, including colon, rectum, breast, and stomach. The suggested dosage is about 500 mg/day.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the administration of a known anti-tumor therapeutic agent, such as 5-FU to the method of JACOBI for the further treatment of cancer. In the absence of unexpected results, it would have been within the scope of the artisan to select any known anti-cancer agent for the combination of benefits.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Monday-Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
April 4, 2003